

EPA REGISTRATION NUMBER 89966-14

PROCESSING REQUEST

Reg # 89966 - Ru

Decision # 528802

Description:

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 3/28/18

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 4/13/2017

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Aswathy Balan

Division: RD

Phone: 347-0510

Date: 3/29/18



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

89966-14

Date of Issuance:

3/28/18

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Thiobencarb Technical

Name and Address of Registrant (include ZIP Code):

James Wagner
Agent for Greenfields Marketing, Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official

Shaja B. Joyner, Product Manager 20
Fungicide-Herbicide Branch
Registration Division 7505P

Date:

3/28/18

2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 89966-14."
3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/13/2017
- Alternate CSF 1 dated 04/13/2017

If you have any questions, please contact Aswathy Balan by phone at 703-347-0510, or via email at balan.aswathy@epa.gov.



Thiobencarb Technical

ACTIVE INGREDIENT:

Thiobencarb:

S-[(4-chlorophenyl)methyl]diethylcarbamothioate 95.9%

OTHER INGREDIENTS: 4.1%**TOTAL:** 100.0%

Contains 0.959 lb. Thiobencarb per pound.

By Weight

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBERS Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: 1-800-222-1222 . For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: 1-800-424-9300 .	
Note To Physician: Thiobencarb is a cholinesterase inhibitor. If signs of cholinesterase inhibition appear, atropine is antidotal.	

EPA Reg. No.: 89966-RU

EPA Est. No.:

Net Contents: _____

Manufactured For:

Greenfields Marketing Ltd.

385 Interlocken Crescent, Suite 240

Broomfield, CO 80021

Product of _____

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into herbicide products for the following uses:

1. **Terrestrial Food Uses:** Rice
2. Uses for experimental purposes that are in compliance with U.S. EPA requirements.
3. This product may be used to formulate products for specific use(s) not listed on the label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

NONREFILLABLE CONTAINERS: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Greenfields Marketing Ltd. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, GREENFIELDS MARKETING LTD. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. To the extent consistent with applicable law, no agent of Greenfields Marketing Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, GREENFIELDS MARKETING LTD. DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT GREENFIELDS MARKETING LTD.'S ELECTION, THE REPLACEMENT OF PRODUCT.

**Thiobencarb Technical**

ACTIVE INGREDIENT: Thiobencarb 3-[(4-chlorophenyl)methyl]diethylcarbamothioate	By Weight 95.9%
OTHER INGREDIENTS:	4.1%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal) call: 1-800-222-1222. For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident) call CHEMTREC: 1-800-424-9300.	
Note To Physician: Thiobencarb is a cholinesterase inhibitor. If signs of cholinesterase inhibition appear, atropine is antidotal.	

EPA Reg. No.: 89966-xx
EPA Est. No.:

Net Contents: _____

Manufactured For:
Greenfields Marketing Ltd.
P.O. Box 115877
Dubai, United Arab Emirates

Product of _____



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed. Wash hands thoroughly before eating, drinking, chewing gum, using tobacco or using the toilet.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.

Only for formulation into herbicide products for the following uses:

1. **Terrestrial Food Uses:** Rice
2. Uses for experimental purposes that are in compliance with U.S. EPA requirements.
3. This product may be used to formulate products for specific use(s) not listed on the label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

Summary of Comments on 89966-RU-EPA Comments.pdf**Page: 1**

Number 1 Author: abalan Subject: Highlight Date: 3/13/2018 1:55:44 PM

Number 2 Author: abalan Subject: Sticky Note Date: 3/13/2018 1:55:58 PM
Delete from all pages

Page: 2

Number 1 Author: abalan Subject: Highlight Date: 3/13/2018 2:04:28 PM

Number 2 Author: abalan Subject: Sticky Note Date: 3/22/2018 1:26:06 PM
Revise as follows:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Number 3 Author: abalan Subject: Highlight Date: 3/13/2018 2:07:52 PM

Number 4 Author: abalan Subject: Highlight Date: 3/22/2018 3:26:27 PM

Number 5 Author: abalan Subject: Sticky Note Date: 3/22/2018 3:26:41 PM
Not required on a technical label, delete

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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Page: 3

Number: 1 Author: abalan Subject: Highlight Date: 3/13/2018 2:04:33 PM

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Greenfields Marketing Ltd. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

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LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT GREENFIELDS MARKETING LTD.'S ELECTION, THE REPLACEMENT OF PRODUCT.

Balan, Aswathy

From: Kt Woodall <ktwoodall@wagnerreg.com>
Sent: Tuesday, March 27, 2018 2:29 PM
To: Balan, Aswathy
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)
Attachments: 89966-RU.20180322.V3 - Clean.pdf; 89966-RU.20180322.V3 - Highlighted.pdf

Hi Aswathy – Clean & Highlighted attached.

Katie Woodall

Wagner Regulatory Associates, Inc.
7217 Lancaster Pike, Suite A
Hockessin, DE 19707
KtWoodall@wagnerreg.com
katie@wagnerreg.com

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Tuesday, March 27, 2018 2:15 PM
To: Kt Woodall <ktwoodall@wagnerreg.com>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Katie,

Please state the **pounds of active per pound of product** underneath the ingredient statements on page 1 for 89966-RU.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Kt Woodall [mailto:ktwoodall@wagnerreg.com]
Sent: Thursday, March 22, 2018 9:12 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: James Wagner <jmw@wagnerreg.com>; Anna Armstrong <Anna@wagnerreg.com>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hello Aswathy – Thank you for all of your help. Attached are Clean & Highlighted versions.

Please let me know if you need anything further.

Warmest regards,

WRA

Katie Woodall

Wagner Regulatory Associates, Inc.
Federal Regulatory Associate
7217 Lancaster Pike, Suite A
Hockessin, DE 19707
KtWoodall@wagnerreg.com
katie@wagnerreg.com

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager. This message contains confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Thursday, March 22, 2018 3:27 PM
To: James Wagner <jmw@wagnerreg.com>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Jim,

Please see the attached label with comments and send the revised label at your earliest convenience.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [<mailto:jmw@wagnerreg.com>]
Sent: Tuesday, March 13, 2018 10:49 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Aswathy,

The CDX email confirmation is attached.

Best regards,

Jim Wagner

Wagner Regulatory Assoc.
Tel: (302) 635-7290
Mobile: (302) 530-5745

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Tuesday, March 13, 2018 10:33 AM
To: James Wagner <jmw@wagnerreg.com>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Jim,

I am still not able to see the submission. Did you receive a confirmation email once you submitted through the portal?
Can you forward that to me?

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [<mailto:jmw@wagnerreg.com>]
Sent: Wednesday, March 07, 2018 8:51 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Aswathy,

I had some problems with CDX yesterday but it was submitted this morning.

Here is the MRID 50542301.

Best regards,

Jim Wagner
Wagner Regulatory Assoc.
Tel: (302) 635-7290
Mobile: (302) 530-5745

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Tuesday, March 06, 2018 7:40 AM
To: James Wagner <jmw@wagnerreg.com>
Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Jim,

Please let me know the new MRID that got assigned to the addendum once you submitted through the portal.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Balan, Aswathy
Sent: Monday, March 05, 2018 7:41 AM

To: 'James Wagner' <jmw@wagnerreg.com>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Yes, please submit through the portal as well.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [mailto:jmw@wagnerreg.com]

Sent: Friday, March 02, 2018 3:49 PM

To: Balan, Aswathy <Balan.Aswathy@epa.gov>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Dear Aswathy,

I am now submitting the additional information requested by Shyam Mathur, copy attached. Please let me know if I should also submit a copy through the CDX portal.

Thank you for your help with this. Please let me know if Shyam will be able to consider this new information in time for the PRIA date.

Best regards,

Jim Wagner

Wagner Regulatory Assoc.
Tel: (302) 635-7290
Mobile: (302) 530-5745

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]

Sent: Wednesday, February 28, 2018 3:30 PM

To: James Wagner <jmw@wagnerreg.com>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Jim,

Just checking if you have any update on this submission.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [mailto:jmw@wagnerreg.com]

Sent: Tuesday, February 20, 2018 9:44 AM

To: Balan, Aswathy <Balan.Aswathy@epa.gov>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Thank you Balan. We will do our best.

Jim Wagner

Wagner Regulatory Assoc.

Tel: (302) 635-7290

Mobile: (302) 530-5745

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]

Sent: Tuesday, February 20, 2018 9:36 AM

To: James Wagner <jmw@wagnerreg.com>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Jim,

After the report gets submitted, the product chemistry reviewer needs to review it. They have closed this current review. A new review needs to be opened again and processed in order to assess this resubmission.

I cannot guarantee that the review will be done by the current PRIA due date. Once you resubmit, I will check with the reviewer how long it will take for their review and then get back to you.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [mailto:jmw@wagnerreg.com]

Sent: Tuesday, February 20, 2018 9:29 AM

To: Balan, Aswathy <Balan.Aswathy@epa.gov>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Dear Aswathy,

Good morning. We are working with the Chinese manufacturer to provide us the additional information needed for discussion of formation of impurities. However this week is Chinese new year celebration and it is delaying the information we need. I think next week we should receive it and I can then submit it to you. My big concern is the PRIA date in early April. I do not want to cause any delay in the approval. Do you think next week will be OK and not delay the PRIA date?

Thanks,

Jim Wagner

Wagner Regulatory Assoc.

Tel: (302) 635-7290

Mobile: (302) 530-5745

From: James Wagner

Sent: Tuesday, February 13, 2018 11:36 AM

To: 'Balan, Aswathy' <Balan.Aswathy@epa.gov>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Thanks! I will work on this today and respond as quickly as I can.

Jim Wagner

Wagner Regulatory Assoc.

Tel: (302) 635-7290

Mobile: (302) 530-5745

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]

Sent: Tuesday, February 13, 2018 11:35 AM

To: James Wagner <jmw@wagnerreg.com>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

See attached.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: James Wagner [<mailto:jmw@wagnerreg.com>]

Sent: Tuesday, February 13, 2018 10:50 AM

To: Balan, Aswathy <Balan.Aswathy@epa.gov>

Subject: RE: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi Aswathy,

Can you please email me a copy of the chemistry review. This will help me understand the problem and how to respond.

Thanks,

Jim Wagner

Wagner Regulatory Assoc.

Tel: (302) 635-7290

Mobile: (302) 530-5745

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]

Sent: Tuesday, February 13, 2018 10:45 AM

To: James Wagner <jmw@wagnerreg.com>

Subject: PRIA application - Thiobencarb Technical (EPA File Symbol: 89966-RU)

Hi James,

The product chemistry review of the subject application identifies a deficiency. The data submitted for guideline 830.1670 (discussion of formation of impurities) is not acceptable. No information regarding the origin of the impurities associated with the technical product produced at the basic manufacturing site was provided.

You need to submit the origin and mechanism of the formation of impurities in the technical manufactured at the basic production site (China).

Please let me know when you can provide this information.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D446215; FILE SYMBOL/REG. No.: 89966-RU(a); PRODUCT NAME: Thiobencarb Technical; DECISION No.: 528802; PC Code(s): 108401; ACTION CODE: R334; FOOD Use: Yes

DATE: March 14, 2018

SUBJECT: Product Chemistry Review of "Thiobencarb Technical"

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

SB Mathur
pubhah
3/14/2018

TO: Aswathy Balan / Shaja Joyner, RM 20
Fungicide-Herbicide Branch / RD (7505P)

REGISTRANT: Greenfields Marketing, Ltd.

MRID NUMBERS: 50542301 Amendment to report under MRID No. 50222201

INTRODUCTION

The product chemistry data for the Thiobencarb technical was reviewed previously (see PCR dated 12-06-2018; MRID Nos. 50222201 to -06; DP 439991) and it was concluded that all the product chemistry data submitted was found to be acceptable, except for the guideline 830.1670 (discussion on the formation of the impurities) for which additional data is required. Wagner Regulatory Associates, on behalf of the applicant Greenfields Marketing, LTD., on March 6, 2018 submitted the required additional information under the MRID No. 50542301 for the guideline 830.1670. CITAB has been asked to determine the acceptability of the additional data submitted for the guideline 830.1670.

SUMMARY OF FINDINGS

830.1670 (discussion on the formation of impurities)

The registrant has provided the mechanisms and origin of the formation of impurities present in the technical thiobencarb as listed on the basic CSF dated August 13, 2017. The mechanisms of formation of all the [REDACTED] listed on the basic CSF have been discussed in detail. Please refer to Confidential appendix for the information discussed.

CONCLUSIONS

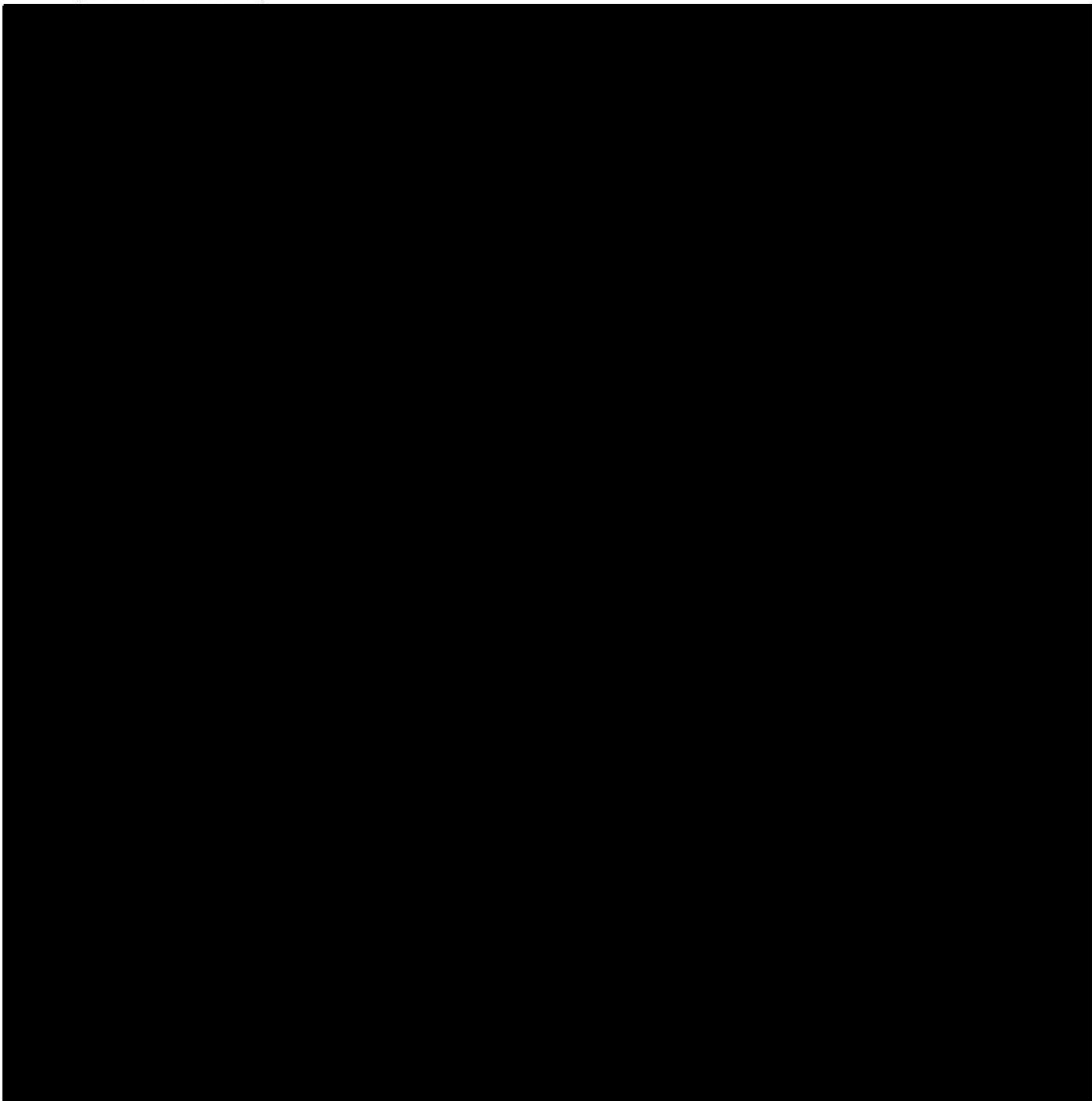
CITAB has evaluated the data provided on the guideline 830.1670 (discussion on the formation of impurities) and has found it to be acceptable.

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: D446213; FILE SYMBOL/REG. No.: 89966-RU(a); PRODUCT NAME: Thiobencarb
Technical; DECISION No.: 528802; PC Code(s): 108401; ACTION CODE: R334; FOOD Use: Yes

CONFIDENTIAL APPENDIX

830.1670 (discussion on the formation of impurities)
(MRID No. 50542301)



Manufacturing process information may be entitled to confidential treatment

Submitted Electronically

March 6, 2018

Document Processing Desk (REGFEE)
ATTN: Ms. Shaja Joyner, PM Team No. 20
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Joyner

**Subject: Greenfields Marketing, Ltd.
Thiobencarb Technical, EPA Reg. No. 89966-RU**

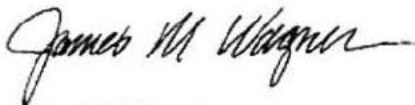
Wagner Regulatory Associates, Inc., as agent for Greenfields Marketing Ltd., is submitting additional information noted below to address a product chemistry deficiency regarding the discussion of formation of impurities, Guideline 830.1670.

The following documents are being submitted electronically via the EPA CDX PSP portal:

- Letter from Greenfields Marketing, Ltd., appointing Wagner Regulatory Assoc., Inc. as its agent
- Data Matrix (internal and public copies) (8570-35)
- Data Transmittal Document
- Data report as outlined in the Transmittal Document

If you have any questions about this submission, please contact the undersigned at 302-635-7290 or at james@wagnerreg.com.

Respectfully Submitted,



James M. Wagner
Agent for Greenfields Marketing, Ltd.
Enclosures



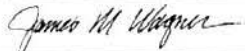
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DATA MATRIX

Date: April 13, 2017		EPA Reg No./File Symbol: 89966-XX R U	Page 1 of 9
Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707		Product: Thiobencarb Technical	
Ingredient: Thiobencarb			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830 Series Group A	Product Identity, Materials, Production Process, Impurities; Certified Limits	50222201	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.1670	Discussion of Formulation of impurities	50542301	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.1700	Preliminary Analysis	50222202 50222203	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.1800	Enforcement Analytical Method	50222202 50222203 50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6302, 6303, 6304	Color, Physical State, Odor	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6313	Stability to normal and elevated temperatures	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6314	Oxidation/Reduction	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6315	Flammability	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6316	Explosibility	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6317	Storage Stability	50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6319	Miscibility	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6320	Corrosion Characteristics	50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6321	Dielectric Breakdown voltage	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.7000	pH	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.7050	UV/Visible Absorption	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	

Signature 	Name and Title Jim Wagner, Agent	Date April 13, 2017
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DATA MATRIX

Date: April 13, 2017				EPA Reg No./File Symbol: 89966-XX		Page 2 of 9	
Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
830.7100	Viscosity	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7200	Melting Point		Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7220	Boiling Point	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7300	Density	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7370	Dissociation Constant	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7520	Particle size, fiber diameter and particle distribution	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7570	Octanol Water Partition Coefficient	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7840	Solubility in Water and Organic Solvents	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7950	Vapor Pressure	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
870.1100	Acute oral toxicity - rat	42130701	Chevron Chemical	Ramon, CA	OLD		
870.1200	Acute dermal toxicity	45104602	Valent USA	Walnut Creek, CA	OLD		
870.1300	Acute inhalation toxicity - rat	44797404	Valent USA	Walnut Creek, CA	OLD		
870.2400	Primary eye irritation - rabbit	81899	The Scotts Company	Marysville, OH	OLD		
870.2500	Primary dermal irritation	44797407	Valent USA	Walnut Creek, CA	OLD		
870.2600	Dermal sensitization	44797408	Valent USA	Walnut Creek, CA	OLD		
870.6100	Delayed neurotoxicity (acute) - hen	84135; 135284	The Scotts Company	Marysville, OH	OLD		
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent			Date April 13, 2017	

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DATA MATRIX

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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
870.6200	Acute neurotoxicity - rat	42987001	Valent USA	Walnut Creek, CA	OLD		
870.3100	90-day Oral - rodent	164576; 116150	International Mineral		OLD		
870.3150	90-day Oral - non-rodent	116151	International Mineral		OLD		
870.3200	21/28-day Dermal	42893001	Valent USA	Walnut Creek, CA	OLD		
870.3465	90-day Inhalation - rat	49119310	K-I Chemical	White Plains, NY	PAY		
870.6200	90-day Neurotoxicity - rat	43001001	Valent USA	Walnut Creek, CA	OLD		
870.4100	Chronic oral - rodent	125717; 148570; 154506; 150894; 150139	The Scotts Company	Marysville, OH	OLD		
870.4200	Carcinogenicity - two rodent species - rat and mouse preferred	86004; 125717; 148570; 154506; 150894; 150139	The Scotts Company	Marysville, OH	OLD		
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	86873; 115248; 13866; 164313	The Scotts Company	Marysville, OH	OLD		
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent			Date April 13, 2017	

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DATA MATRIX

Date: April 13, 2017

EPA Reg No./File Symbol:
89966-XX

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Applicant's/ Registrant's Name & Address:
 Greenfields Marketing, Ltd.
 c/o Wagner Regulatory Associates Inc.
 P.O. Box 640, Hockessin, DE 19707

Product:
Thiobencarb Technical

Ingredient: Thiobencarb

870.38	Reproduction and fertility effects	154507; 40446201	The Scotts Company	Marysville, OH	OLD	
870.63	Developmental neurotoxicity				GAP	
870.51	Bacterial reverse mutation assay	84131	The Scotts Company	Marysville, OH	OLD	
870.53	In vitro mammalian cell assay	40352401; 46059801;	The Scotts Company Valent USA	Marysville, OH Walnut Creek, CA	OLD; PAY	
870.5385	In vivo cytogenetics	40352402	The Scotts Company	Marysville, OH	OLD	
870.5395	In vivo cytogenetics	84132	The Scotts Company	Marysville, OH	OLD	
870.7485	Metabolism and pharmacokinetics	87202; 42340302; 49119309	The Scotts Company K-I Chemical K-I Chemical	Marysville, OH White Plains, NY	OLD; PAY	
870.7600	Dermal penetration	45206001 49828403; 49828404	K-I Chemical Valent USA Valent USA	Walnut Creek, CA	PAY	
870.7800	Immunotoxicity	49119311	K-I Chemical	White Plains, NY	PAY	
850.2100	Avian oral toxicity	49681002; 42600201	K-I Chemical	White Plains, NY	PAY OLD	
850.2200	Avian dietary toxicity	25779; 34763 44846206	The Scotts Company Valent USA	Walnut Creek, CA	OLD	

Signature

James M. Wagner

Name and Title
Jim Wagner, Agent

Date
April 13, 2017

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Date: April 13, 2017

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Applicant's/ Registrant's Name & Address:
 Greenfields Marketing, Ltd.
 c/o Wagner Regulatory Associates Inc.
 P.O. Box 640, Hockessin, DE 19707

Product:
 Thiobencarb Technical

Ingredient: Thiobencarb

850.23	Avian reproduction	43075401; 45140601;	Valent USA	Walnut Creek, CA	OLD	
850.101	Acute toxicity daphnia	25788; 25789; 79118	The Scotts Company	Marysville, OH	OLD	
850.1025	Acute toxicity oyster	25784; 25785; 79114; 79115	The Scotts Company	Marysville, OH	OLD	
850.1035	Acute toxicity mysid	25787	The Scotts Company	Marysville, OH	OLD	
850.1045	Acute toxicity penaeid	25787	The Scotts Company	Marysville, OH	OLD	
850.1055	Acute bivalve embryo larvae	79115	The Scotts Company	Marysville, OH	OLD	
850.1075	Freshwater fish toxicity	25783; 49681001	Th Scotts Company K-I Chemical	Marysville, OH White Plains, NY	OLD PAY	
850.1300	Aquatic invertebrate life cycle (freshwater) daphnia	42680401	K-I Chemical	White Plains, NY	OLD	
850.1350	Aquatic invertebrate life cycle (saltwater)	25787	The Scotts Company	Marysville, OH	OLD	
850.1400	Fish early-life stage (freshwater)				GAP	
850.1400	Fish early-life stage (saltwater)				GAP	
850.1500	Fish life cycle	49975901; 49119306	K-I Chemical	White Plains, NY	PAY	
850.1710	Aquatic organisms bioavailability, biomagnification, toxicity	139051; 42460401	k-I Chemical The Scotts Company	White Plains, NY	OLD	
850.1950	Simulated or actual field testing for aquatic organisms	165066; 139048; 43442501	Valent USA	Walnut Creek, CA	OLD	
850.1735	Whole sediment: acute freshwater invertebrates 10 day	44628602	Valent USA	Walnut Creek, CA	OLD	

Signature

Name and Title
 Jim Wagner, Agent

Date
 April 13, 2017

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DATA MATRIX

Date: April 13, 2017				EPA Reg No./File Symbol: 89966-XX		Page 6 of 9
Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical		
Ingredient: Thiobencarb						
850.1740	Whole sediment: acute marine invertebrates 10 day				GAP	
850.1740	Whole sediment: chronic invertebrates freshwater and marine	46091402	Valent USA	Walnut Creek, CA	OLD	
850.3020	Honeybee acute contact toxicity	46059804	Valent USA	Walnut Creek, CA	OLD	
850.3030	Honey bee toxicity of residues on foliage				GAP	
850.3040	Field testing for pollinators				GAP	
850.4200 850.4225 850.4250	Seed Germination, Seed Emergence and Vegetative Vigor	41690902; 44846201	Chevron Chemical; Valent USA	Ramon, CA Walnut Creek, CA	OLD	
850.4400 850.4500	Aquatic Plant Toxicity	41215308; 41690901	Chevron Chemical; The Scotts Company	Ramon, CA Marysville, OH	OLD	
835.2120	Hydrolysis	42130704	Chevron Chemical	Ramon, CA	OLD	
835.2240	Photodegradation in water	42257801	K-I Chemical	White Plains, NY	OLD	
835.2410	Photodegradation on soil	41215312	The Scotts Chemical	Marysville, OH	OLD	
835.4100	Aerobic soil	42015301; 43300401; 49119303	Valent USA Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD OLD PAY	
835.4200	Anaerobic soil	43252001; 49119301	Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD PAY	
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent		Date April 13, 2017	

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Date: April 13, 2017				EPA Reg No./File Symbol: 89966-XX		Page 7 of 9	
Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
835.4300	Aerobic aquatic	49119302	K-I Chemical	White Plains, NY	PAY		
835.4400	Anaerobic aquatic	49119304	K-I Chemical	White Plains, NY	PAY		
835.1230	Leaching and adsorption/desorption	43150601; 43121201	Valent USA	Walnut Creek, CA	OLD		
835.1240	Leaching and adsorption/desorption	49828402	Valent USA	Walnut Creek, CA	PAY		
835.1410	Volatility - laboratory	124730; 44493; 49924	The Scotts Company	Marysville, OH	OLD		
835.8100	Volatility - field				GAP		
835.6100	Terrestrial	155451; 42003404	The Scotts Company; Chevron Chemical	Marysville, OH	OLD		
835.6200	Aquatic (sediment)	43404005	Valent USA	Walnut Creek, CA	OLD		
835.2120	Hydrolysis	42130704	Chevron Chemical	Ramon, CA	OLD		
835.2240	Photodegradation in water	42257801	K-I Chemical	Walnut Creek, CA	OLD		
835.2410	Photodegradation on soil	41215312	The Scotts Chemical	Marysville, OH	OLD		
835.4100	Aerobic soil	42015301; 43300401; 49119303	Valent USA Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD OLD PAY		
835.4200	Anaerobic soil	43252001; 49119301	Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD PAY		
835.4300	Aerobic aquatic	49119302	K-I Chemical	White Plains, NY	PAY		
835.4400	Anaerobic aquatic	49119304	K-I Chemical	White Plains, NY	PAY		
835.1230	Leaching and adsorption/desorption	43150601; 43121201	Valent USA	Walnut Creek, CA	OLD		
835.1240	Leaching and adsorption/desorption	49828402	Valent USA	Walnut Creek, CA	PAY		
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent			Date April 13, 2017	



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EPA Reg No./File Symbol:
89966-XX

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Applicant's/ Registrant's Name & Address:
 Greenfields Marketing, Ltd.
 c/o Wagner Regulatory Associates Inc.
 P.O. Box 640, Hockessin, DE 19707

Product:
Thiobencarb Technical

Ingredient: Thiobencarb

835.1410	Volatility - laboratory	124730; 44493; 49924	The Scotts Company	Marysville, OH	OLD	
835.8100	Volatility - field				GAP	
835.6100	Terrestrial	155451; 42003404	The Scotts Company; Chevron Chemical	Marysville, OH Ramon, CA	OLD	
835.6200	Aquatic (sediment)	43404005	Valent USA	Walnut Creek, CA	OLD	
860.1300	Nature of the residue in plants	42384701	K-I Chemical	White Plains, NY	OLD	
860.1300	Nature of the residue in livestock	42340301; 43404002; 43492301	K-I Chemical; Valent USA; Valent USA	White Plains, NY Walnut Creek, CA	OLD	
860.1850	Confined rotational crops				GAP	
860.1340	Residue analytical methods	42023; 42024; 47614; 47615; 47616; 47617; 47618	The Scotts Company	Marysville, OH	OLD	
860.1360	Multiresidue method	43075402	Valent USA	Walnut Creek, CA	OLD	
860.1380	Storage stability	42003405; 42384702	Chevron; K-I Chemical	White Plains, NY	OLD	
860.1500	Crop field trials	124233; 124278; 40774601; 40774602; 42384702	The Scotts Company The Scotts Company K-I Chemical; The Scotts Company; The Scotts Company	Marysville, OH White Plains, NY	OLD	

Signature

James M. Wagner

Name and Title
Jim Wagner, Agent

Date
April 13, 2017



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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
860.1520	Processed food or feed	42987002	Valent USA	Walnut Creek, CA	OLD		
860.1480	Meat/milk/poultry/eggs	125228; 42962801	The Scotts Company Valent USA	Marysville, OH Walnut Creek, CA	OLD		
860.1400	Potable water	43404003	Valent USA	Walnut Creek, CA	OLD		
860.1400	Fish	139051; 42460401	k-I Chemical The Scotts Company	White Plains, NY Marysville, OH	OLD		
860.1400	Irrigated crops	43148201; 43404001	Valent USA	Walnut Creek, CA	OLD		
860.1900	Field rotational crops	39114; 41609011	The Scotts Company; Chevron Chemical	Marysville, OH	OLD		
Subpart K - Human Exposure (Series 875)	Applicator Exposure and Post Application Exposure Data	CITE ALL	Ag Handlers Exposure Task Force Ag Reentry Exposure Task Force	Macon, MO Washington, DC	PAY		
Subpart L - Spray Drift	Spray Drift Data	CITE ALL	Spray Drift Task Force	Washington, DC	OLD		
Signature <i>James M. Wagner</i>		Name and Title Jim Wagner, Agent			Date April 13, 2017		

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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 22, 2018

Subject: Thiobencarb Technical
EPA File Symbol: 89966-RU
DP Barcode: 439992
Action Code: R334
Submission #: 1002230
E-Sub #: 18957
PC Code: 108401 (Thiobencarb: 95.9%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
Feb - 22 - 2018

Through: P.V. Shah, Ph.D., Branch Chief
CITAB
Registration Division (7505P)

P.V. Shah
2/22/2018

To: Lisa Pahel/Shajah Joyner, RM 20
Fungicide and Herbicide Branch
Registration Division (7505P)

Registrant: GREENFIELDS MARKETING LTD.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
108401 Thiobencarb: S-[(4-chlorophenyl)methyl]diethylcarbamothioate.....	95.9%
Other Ingredients:	4.1%
TOTAL:	100.0%

ACTION REQUESTED: "Greenfields Marketing Ltd. has submitted an application for the registration of a MUP containing the active ingredient thiobencarb. This is a primary application linked to three secondary applications (87290-TG, 87290-TU, 87290-TL). They are claiming similarity to 63588-4. Please review the cited acute tox data to determine if the application is acceptable from an acute tox standpoint.

“Included in this package are the applicant’s cover letter, data transmittal, proposed Basic and Alternate CSF #1. The label, data matrix, and additional documents can be found in Documentum under e-submission #18957...”

BACKGROUND: The material available to CITAB includes a cover letter dated April 13, 2017, a form 8570-1 stating that this product is similar or identical in composition and labeling to EPA Reg. No. 63588-4, a proposed label (signal word: CAUTION), a data matrix which cites (page 2) the following MRIDs to satisfy the acute toxicity data requirements: 42130701 (870.1100), 45104602 (870.1200), 44797404 (870.1300), 81899 (870.2400), 44797407 (870.2500) and 44797408 (870.2600). In addition, there are CSFs for a Basic Formulation and an Alternate Formulation (both are dated April 13, 2017).

COMMENTS AND RECOMMENDATIONS:

1. The oral toxicity study in MRID 42130701 (male rat LD₅₀ = 1033 mg/kg; female rat LD₅₀ = 1130 mg/kg) was cited in the December 1997 Thiobencarb Reregistration Eligibility Decision, with assignment of technical thiobencarb to toxicity category III by this exposure route.
2. This reviewer has been unable to find a previous review of MRID 45104602. An examination of this document indicates there were no mortalities in 5M and 5F Sprague-Dawley rats which received a 24-hour dermal exposure to technical thiobencarb, indicating toxicity category IV by this exposure route.
3. This reviewer has been unable to find a previous review of MRID 44797404. An examination of this document indicates there were no mortalities in 5M and 5F Sprague-Dawley rats which received nose-only exposure to an atmosphere containing 2.43 mg/L. The MMAD was 2.5 µm and the GSD was 2.2. Technical thiobencarb is in toxicity category IV by this exposure route.
4. The cited eye irritation study is MRID 81899. This document is illegible. This study was reviewed (TXR 0000140) on March 24, 1975, with the comment: “conjunctival irritation at 48 hrs. All normal by 7 days. No corneal opacity.” Based on this comment, assignment is to toxicity category III by this exposure route. It is also noted that the December 1997 Thiobencarb Reregistration Eligibility Decision assigns technical thiobencarb to toxicity category III for eye exposure (the citation is to MRID 00040581).
5. This reviewer has been unable to find a previous review of the cited dermal irritation study in 44797407. An examination of this document indicates the PDII was 0.4, with all scores zero at 72 hours. Technical thiobencarb is in toxicity category IV by this exposure route.
6. This reviewer has been unable to find a previous review of the cited dermal sensitization study in 44797408. An examination of this document indicates this study was conducted in guinea pigs using a Buehler protocol, and the test material was not a sensitizer.

7. Based on the results of the cited acute toxicity studies, the following is the acute toxicity profile for both 89966-RU (Thiobencarb Technical):

Acute oral LD ₅₀ (rat)	III	cited	MRID 42130701
Acute dermal LD ₅₀ (rat)	IV	cited	MRID 45104602
Acute inhalation LC ₅₀ (rat)	IV	cited	MRID 44797404
Eye irritation (rabbit)	III	cited	MRID 81899
Skin irritation (rabbit)	IV	cited	MRID 44797407
Dermal sensitization (g. pig)	Negative	cited	MRID 44797408

8. Based on the acute toxicity profile, as well as information from the CSF and proposed label, the following is the precautionary and first aid labeling for 89966-RU:

PRODUCT ID #: 089966-00014

PRODUCT NAME: THIOBENCARB TECHNICAL

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing. Wear (specify appropriate protective eyewear such as goggles, face shield, or safety glasses, if appropriate).*

**Optional statement.*

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

As part of the first aid statements, the registrant has proposed the following: "Note to Physician: Thiobencarb is a cholinesterase inhibitor. If signs of cholinesterase inhibition appear, atropine is antidotal." This statement is appropriate and consistent with the requirements of PR Notice 2001-1.

9. All acute toxicity data requirements for the registration of 89966-RU have been satisfied by the citations to MRIDs 42130701, 45104602, 44797404, 00081899, 44797407 and 44797408.
10. The proposed Basic and Alternate Formulation CSFs and any chemistry data for EPA File Symbol 89966-RU must also be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D439991; FILE SYMBOL/REG. No.: 89966-RU; PRODUCT NAME: Thiobencarb Technical; DECISION No.: 528802; PC Code(s): 108401; ACTION CODE: R334; FOOD Use: Yes

DATE: December 6, 2017

SUBJECT: Product Chemistry Review of "Thiobencarb Technical"

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

TO: *Aswathy* Lisa Pahal / Shaja Joyner, RM 20
Fungicide-Herbicide Branch / RD (7505P)

REGISTRANT: Greenfields Marketing, Ltd.

MRID Numbers: 50222201, 50222202, 50222203, 50222204, 50222205, 50222206

INTRODUCTION:

The applicant submitted an application for approval of the new manufacturing-use product "Thiobencarb Technical." There are two manufacturing sources for this product. The basic source is [REDACTED] and the alternate source is [REDACTED]. In support of the application, the applicant submitted Group A product chemistry data with MRID Nos. 50222201 through 50222203 and Group B product chemistry data with MRID Nos. 50222204 and 50222206. The basic CSF [REDACTED] and Alternate CSF [REDACTED] both dated 04/13/2017) were also submitted for the product. CITAB has been asked to determine the acceptability of the product chemistry data, and basic and alternate CSFs.

Note that this application is linked to three secondary applications, which are being reviewed concurrently, for these three products "Willowood Thionil EC (EPA Reg. No. 87290-TG)," Willowood Thioben 8EC (EPA Reg. No. 87290-TU)," and "Willowood Thio UltraMax (EPA Reg. No. 87290-TL)."

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 50222201). The nominal concentrations of the active ingredient listed on the basic CSF and Alternate CSF match respectively the averages obtained from the 5-batch preliminary analysis of the product produced at the basic and alternate manufacturing sites. The content of the A.I. given on the product label (95.9%) matches with the NC of the AI (95.5%) on the proposed basic CSF and the NC of the AI (98.4%) on the proposed Alternate CSF #1 falls within the certified limits of the product label claim nominal concentration. The information presented meets the data requirements for 40 CFR§158.320.

Product ingredient source information may be entitled to confidential treatment

DP BARCODE No.: D439991; **FILE SYMBOL/REG. No.:** 89966-RU; **PRODUCT NAME:** Thiobencarb
Technical: **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

830.1600: (description of materials used to produce the product)

The submitted data are acceptable. MSDSs of all the starting materials, and their suppliers and specifications are provided in the study (MRID 50222201). The information presented meets the data requirements for 40 CFR§158.325.

830.1620 (description of production process)

Descriptions of the production processes at both basic and alternate manufacturing sites, chemical pathways, and flow charts were provided in MRID 50222201. The active ingredient was [REDACTED] for basic formulation, whereas, [REDACTED] was used in the alternate production site. Details of the processes for the both the sites have been provided. The information presented meets the data requirements for 40 CFR§158.330.

830.1670 (discussion on the formation of impurities)

The submitted data are acceptable. Potential impurities were identified and quantified as part of the five-batch analysis of the product produced at both manufacturing sites (MRIDs 50222202 and 50222203). The origins of the impurities in Thiobencarb Technical produced at the alternate manufacturing site were provided (MRID 50222201). However, no discussion on the origins of the impurities obtained from the basic manufacturing site was submitted. There are no impurities of toxicological concern present in Thiobencarb Technical. The information presented meets the data requirements for 40 CFR§158.340.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for two five-batch analyses of the product produced at both manufacturing sites (MRIDs 50222202 and 50222203). The nominal concentrations of the A.I. at the basic manufacturing source were: 95.88, 95.78, 95.88, 95.92, and 95.97% (average 95.89%, from Page 8 of 486 in MRID 50222202). The nominal concentrations of the A.I. at the alternate manufacturing source were: 98.64, 98.33, 98.37, 98.50 and 98.66% (average 98.50%, from Page 17 of 140 in MRID 50222203). The information presented meets the data requirements for 40 CFR§158.345.

830.1750 (certified limits)

The submitted data are acceptable. The nominal concentrations for the A.I. and impurities on both basic and alternate CSFs were respectively established based on the results from the five-batch analysis of Thiobencarb Technical produced at both basic and alternate manufacturing sites (MRIDs 50222202 and 50222203). The upper and lower certified limits for the A.I., and the upper certified limits for the impurities on both basic and alternate CSFs are within EPA's Standard Certified Limits. The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

830.1800 (enforcement analytical method)

The submitted data are acceptable. The analytical method for quantifying the A.I. in five representative batches of Thiobencarb Technical produced at the basic manufacturing site is HPLC-UV with a photodiode array detector and external standard calibration, which was validated for specificity, linearity, and precision, but not for accuracy (MRID 50222202). The identification methods for the A. I. include FT-IR, MS, UV and NMR (MRID 50222202). Impurities were identified using FT-IR, MS, UV and NMR, and quantified by HPLC-PDA.

DP BARCODE No.: D439991; **FILE SYMBOL/REG. No.:** 89966-RU; **PRODUCT NAME:** Thiobencarb Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

The analytical method for quantifying the A.I. in five representative batches of Thiobencarb Technical produced at the alternate manufacturing site is GC-FID with internal standard calibration, which was validated for specificity/selectivity, linearity and precision, but not for accuracy (MRID 50222203). The identification methods for the A. I. include FI-IR, GC-MS and NMR (MRID 50222203). The impurities were identified using GC-MS, and quantified by GC-FID.

2. Group B guidelines (physical-chemical properties):

The registrant submitted data for color, physical state, odor, stability to normal and elevated temperatures/metals/metal ions, oxidation/reduction, pH, UV/Visible absorption, viscosity, boiling point, and density (MRID 50222204). Accelerated storage stability and corrosion characteristics studies were conducted at 54°C (MRID 50222205). Literature data were cited for partition coefficient, water solubility and vapor pressure (MRID 50222206). Waivers were requested for flammability, explosability, miscibility, dielectric breakdown voltage, melting point, dissociation constant in water, and particle size/fiber diameter/particle distribution, and adequate justification was given for the waivers (MRID 50222206).

CONCLUSIONS:

The CITAB has reviewed the proposed basic and alternate CSFs, and the supporting group A and group B data for Thiobencarb Technical and has concluded that:

1. The product chemistry data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process) and 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.
2. The data submitted for guideline 830.1670 (discussion of the formation of impurities) are not acceptable. No information regarding the origins of the impurities associated with the technical product produced at the basic manufacturing site was provided. The registrant must submit the origin and mechanism of the formation of impurities in the technical thiobencarb manufactured at the basic production site (China).
3. The proposed basic CSF (dated 04/13/2017) and Alternate CSF (dated 04/13/2017) are acceptable. The upper and lower certified limits for the A.I. and impurities are within EPA's Standard Certified Limits
4. The group B product chemistry (physical-chemical characteristics) data submitted for the technical Thiobencarb are acceptable.
5. The Agency concurs with the results of the QSAR Prediction study conducted by the registrant on the impurities. Based on the predicted or experimental acute oral toxicity values for the impurities, all are less toxic or approximately equi-toxic to Thiobencarb Technical with the exception of [REDACTED]. The latter is somewhat more toxic but the predicted value is within Toxicity Category II which is not considered to be highly toxic. Additionally, all of the impurities are predicted or known from experimental data to be negative for mutagenicity. It is therefore concluded that none of the impurities identified in the five batch preliminary analysis are of toxicological concern.

Manufacturing process information may be entitled to confidential treatment

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Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

830.1550. Product identity & composition: (MRID No. 50222201)

Common Name: Thiobencarb

IUPAC Name: *S*-[(4-chlorophenyl)methyl] *N,N*-diethylcarbamothioate

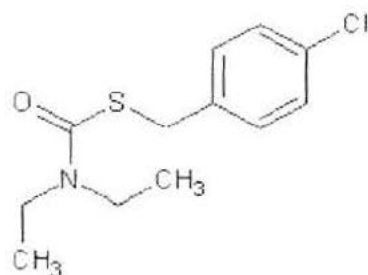
CAS Name: *S*-4-chlorobenzyl diethyl(thiocarbamate)

CAS Number: 28249-77-6

Molecular formula: $C_{12}H_{16}ClNOS$

Molecular weight: 257.77 g/mole

Structural formula:



DP BARCODE No.: D439991; **FILE SYMBOL/REG. No.:** 89966-RU; **PRODUCT NAME:** Thiobencarb Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

Group A Product Chemistry Data

Table 1. Manufacturing and Impurity Data for "Thiobencarb Technical"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50222201	A	Adequately described
830.1600	Description of materials used to produce the product	50222201	A	MSDSs of the starting materials, and their suppliers and specifications were provided.
830.1620	Description of production process	50222201	A	Detailed description of the production process was provided for both the production sites.
830.1670	Discussion of formation of impurities	50222201	U	The origins of the impurities associated with the technical product produced at the basic manufacturing site were not discussed.
830.1700	Preliminary analysis	50222202 and 50222203	A	Five-batch analyses of the A.I. at both basic and alternate manufacturing sites were provided.
830.1750	Certified limits	Basic CSF (dated 04/13/2017), Alternate CSF (dated 04/13/2017)	A	The certified limits for the A.I. and impurities on both basic and alternate CSFs are within EPA's Standard Certified Limits.
830.1800	Enforcement analytical method	50222202, 50222203, 50222205	A	The validated analytical method was provided for the methods for quantifying the A.I. were not validated for accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties for "Thiobencarb Technical"				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	50222204	A	Light Reddish Brown
830.6303	Physical state	50222204	A	Liquid
830.6304	Odor	50222204	A	Mildly Sour
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions	50222205 50222206	A	The product was stable for 14 days at 54°C. The product is not expected to come into contact with metals and metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	50222204	A	The product is compatible with water, 5% w/v ammonium phosphate, iron powder, and aromatic 100 fluid, but incompatible with 5% w/v potassium permanganate.
830.6315	Flammability	50222206	W	The product does not contain flammable components.
830.6316	Explodability	50222206	W	The product does not have the chemical bonds or functional groups associated with explosive chemicals.
830.6317	Accelerated storage stability	50222205	A	The 14-day accelerated storage stability study showed that the product was stable for 14 days at 54°C when stored in HDPE containers.
830.6319	Miscibility	50222206	W	The product is not an emulsifiable liquid to be diluted with petroleum solvent.
830.6320	Accelerated corrosion characteristics	50222205	G	The 14-day accelerated corrosion characteristics study showed that no corrosion and weight change of the containers were observed at 54°C when stored in HDPE containers.
830.7000	pH	50222204	A	5.60 at 25°C
830.7050	UV/Visible absorption	50222204	A	ϵ (202.05, 220.84 nm) = 29000, 19000 (neutral condition); ϵ (201.02, 220.85 nm) = 31000, 19000 (acidic condition); ϵ (220.27 nm) = 19000 (alkaline condition).
830.7100	Viscosity	50222204	A	19.9 centipoise at 25°C 11.1 centipoise at 39°C
830.7200	Melting point	50222206	W	Not applicable, the product is a liquid.
830.7220	Boiling point	50222204	A	128 - 139°C
830.7300	Density	50222204	A	1.165 g/cm ³ (9.72 pounds/gallon) at 25°C 1.150 g/cm ³ (9.60 pounds/gallon) at 39°C
830.7370	Dissociation constants in water (DC)	50222206	W	The product does not dissociate.
830.7550	Partition coefficient	50222206	A	Log P _{ow} = 3.4
830.7840	Water solubility	50222206	A	28 mg/L (25°C)
830.7950	Vapor pressure	50222206	A	0.000022 mmHg at 25°C
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers				

DP BARCODE No.: D4399, **FILE SYMBOL/REG. No.:** 89966-RU; **PROJECT NAME:** Thiobencarb Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

830.1800 (enforcement analytical method)
(MRID Nos. 50222202 and 50222203)

The analytical method for quantifying the A.I. in five representative batches of Thiobencarb Technical produced at the basic manufacturing site is HPLC-UV with a photodiode array detector and external standard calibration, which was validated for specificity, linearity, and precision, but not for accuracy (MRID 50222202). The identification methods for the A. I. include FT-IR, HPLC-MS, UV and NMR (MRID 50222202).

The Impurities were identified using FT-IR, HPLC-MS, UV and NMR, and quantified by HPLC-PDA. The identities of IMP-1 and IMP-3 were also confirmed by GC-MS. The quantification method for these four impurities (IMP-1, IMP-2, IMP-3 and IMP-4) was validated for specificity, linearity, precision, and accuracy. The quantification method for these three impurities (IMP-5, IMP-6 and IMP-7) was validated for specificity, linearity, precision, accuracy, LOD and LOQ. The "Material insoluble in acetone" was quantified by weighing. The water content was determined by the Karl-Fischer titration method.

The registrant provided the following information for quantifying the active ingredient in Thiobencarb Technical produced at the basic manufacturing site [REDACTED] (MRID 50222202).

Product ingredient source information may be entitled to confidential treatment

4.1 Preliminary analysis of the test substance

4.1.1 Outline

Five batches of test substances were analysed by reverse phase HPLC. The impurities equal or greater than 0.06% area were marked.

4.1.2 Reagents

Thiobencarb Reference substance, purity 98.0%, Lot No.: 40603, supplied by Dr. Ehrenstorfer GmbH, Germany;

IMP-1 Reference substance, purity 97.23%, Lot No.: WG0212692-170123001, supplied by Bide Pharmatech Ltd., China;

IMP-2 Reference substance, purity 99.89%, Lot No.: 2017030701S, supplied by Jiangsu Sinography Testing Co., Ltd., China;

IMP-3 Reference substance, purity 98.00%, Lot No.: 2017030705S, supplied by Jiangsu Sinography Testing Co., Ltd., China;

IMP-4 Reference substance, purity 97.53%, Lot No.: 2017030704S, supplied by Jiangsu Sinography Testing Co., Ltd., China;

IMP-5 Reference substance, purity 97.0%, Batch No.: 20170110, supplied by Raw Material Medicin Reagent Co., Ltd., China;

IMP-6 Reference substance, purity 99.75%, Lot No.: 2017030702S, supplied by Jiangsu Sinography Testing Co., Ltd., China;

IMP-7 Reference substance, purity 97.89%, Lot No.: 2017030703S, supplied by Jiangsu Sinography Testing Co., Ltd., China;

Acetonitrile, HPLC grade, purity $\geq 99.9\%$, Lot No.: 16030551, supplied by TEDIA, USA;

Ultrapure Water, Resistivity: 18.20 M Ω ·cm, prepared by ultrapure water purification system.

4.1.3 Equipment

HPLC system, 2695D separation module with 2996 PDA, supplied by Waters, USA;

Data processing software system, Empower 2.0, supplied by Waters, USA;

Electronic Balance, model: NewClassic MS105, supplied by Mettler Toledo, Switzerland;

Ultrasonic water bath, model: KH-500B, supplied by Kunshan Hechuang Co., Ltd., China;
Volumetric flask, 10 mL, 50 mL, supplied by Shanghai Shenbo Glass Instrument Co., Ltd., China;
Nylon syringe filters, 0.22 µm, 13 mm, supplied by Bonna-Agela Technologies Inc., China;
Disposable syringe, 5 mL, supplied by Jiangyin Huada Medical Products Co., Ltd., China;
Measuring cylinder, 10 mL, 50 mL, supplied by Shanghai Shenbo Glass Instrument Co., Ltd., China;
Ultrapure water purification system, model: Cascada LS MK2, supplied by Pall Corporation, USA.

4.1.4 Analytical condition

Column: Waters XBridge C18 column, 4.6 × 150 mm, particle size: 3.5 µm, serial No.: 01773601413845

Injection volume: 5 µL

Mobile phases:

Time (min)	Composition (% v/v)	
	Acetonitrile	Ultrapure Water
0	35	65
10	35	65
12	60	40
38	60	40
39	90	10
44	90	10
45	35	65
50	35	65

Flow rate: 1.0 mL/min

Column Temperature: 35 °C

Detector: PDA

Wavelength: 233 nm (for quantitation), 210 to 400 nm (for 3D spectrogram)

Run time: 50 min

4.1.5 Preliminary analysis

I) Sample solution preparation

31.05 mg, 30.87 mg, 30.60 mg, 29.21 mg and 29.11 mg of each batch of technical grade Thiobencarb samples (the batch of 161030, 161101, 161023, 161025 and 161028 separately) were weighed into five separate 10 mL volumetric flasks. About 8 mL acetonitrile was added into the flasks and the flasks were placed in the running ultrasonic water bath until the substances were dissolved. The solutions were allowed to equilibrate to room temperature (25±5 °C) and made up to the mark using acetonitrile and mixed well. The solutions were filtered through 0.22 µm filter and injected into HPLC. Coded these solutions as PRE-B1, PRE-B2, PRE-B3, PRE-B4 and PRE-B5.

III) Thiobencarb reference solution preparation

20.29 mg Thiobencarb reference substance was weighed into a 50 mL volumetric flask. About 40 mL acetonitrile was added into flask and the flask was placed in the running ultrasonic water bath until the

substances were dissolved. The solution was allowed to equilibrate to room temperature (25±5 °C) and made up to the mark using acetonitrile and mixed well. Coded this solution as STD-AI.

4.6.6 Determination of active ingredient content in test substance

Test substance solutions preparation was referred to 4.1.5 I) Sample solution preparation. Details of test substance solution preparation are listed as below:

Batch No.	Weight of test substance (mg)	Dilute volume (mL)	Solution Name
161030	19.95	50	QUA-AI-B1-1
	20.03	50	QUA-AI-B1-2
161101	20.04	50	QUA-AI-B2-1
	20.09	50	QUA-AI-B2-2
161023	19.97	50	QUA-AI-B3-1
	19.95	50	QUA-AI-B3-2
161025	20.20	50	QUA-AI-B4-1
	20.12	50	QUA-AI-B4-2
161028	19.98	50	QUA-AI-B5-1
	21.35	50	QUA-AI-B5-2

Injected duplicate calibration solutions (Lin-AI-STD3 and AI-STD) bracketing the duplicate injections of each sample solutions into the HPLC after filtered through 0.22 µm filter.

4.6.7 Calculation

$$\text{Response factor } f = C/A_{\text{std}} \quad C = W_{\text{std}} \cdot P_1/V$$

$$\text{Active ingredient content } C \text{ (g/kg)} = A_{\text{spl}} \cdot f \cdot V \cdot 1000/W_{\text{spl}}$$

Where:

A_{std} = peak area of Thiobencarb in the calibration solution (µV·sec)

A_{spl} = peak area of Thiobencarb in the sample solution (µV·sec)

W_{std} = weight of reference substance taken (mg)

W_{spl} = weight of test substance taken (mg)

V = volume of solution (L)

P_1 = purity of Thiobencarb reference substance (%)

The analytical method for quantifying the A.I. in five representative batches of Thiobencarb Technical produced at the alternate manufacturing site is GC-FID with internal standard calibration, which was validated for specificity/selectivity, linearity and precision, but not for accuracy (MRID 50222203). The identification methods for the A. I. include FT-IR, GC-MS and NMR (MRID 50222203).

The impurities were identified by GC-MS, and quantified by GC-FID. The quantification methods were validated for specificity/selectivity, linearity, accuracy, precision, LOD and LOQ (MRID 50222203). The

DP BARCODE No.: D4399, FILE SYMBOL/REG. No.: 89966-RU; PRODUCT NAME: Thiobencarb
 Technical; DECISION No.: 528802; PC Code(s): 108401; ACTION CODE: R334; FOOD Use: Yes

"Material insoluble in acetone" was quantified by weighing. The water content was determined by the Karl-Fischer titration method.

The registrant provided the following information for quantifying the active ingredient in Thiobencarb Technical produced at the alternate manufacturing site [REDACTED] (MRID 50222203).

6.6 Analytical Method

6.6.1 GC-FID Parameter (Active Ingredient Analysis)

Chromatographic Conditions: (For Active Ingredient and Impurities)

Column: DB-1701 [30m x 0.25 mm i.d (capillary), 0.25 µm film thickness]

Carrier gas: Nitrogen

Detector: FID

Oven temperature: 70 °C hold for 2 minutes, 20°C/min to 270°C, hold for 6 minutes

Oven temperature(For Diethyl amine): 50 °C hold for 3 minutes, 20°C/min to 270°C, hold for 6 minutes

Detector temperature: 270°C

Injector temperature: 225°C

H₂ flow: 30 mL/minute

Air flow: 300 mL/minute

Makeup flow: 25 mL/minute

Nitrogen flow: 2.0 mL/minute

Split ratio: 25:1

Injection volume: 2 µL

Run time: 18 minutes

Run time (For Diethyl amine): 20 minutes

Diluent: Acetone, Toluene (For Diethyl amine)

7.8.3 Preparation of Sample - Active Substance

Sample ID	Weight Taken (mg)	Diluent	Final Volume (mL)	Sample ID
D553-001/A	37.74	IS Solution	50	Sample A
D553-001/B	38.47	IS Solution	50	Sample B
D553-001/C	38.26	IS Solution	50	Sample C
D553-001/D	37.88	IS Solution	50	Sample D
D553-001/G	37.98	IS Solution	50	Sample E

The content of the active ingredient is calculated by using the formula below.

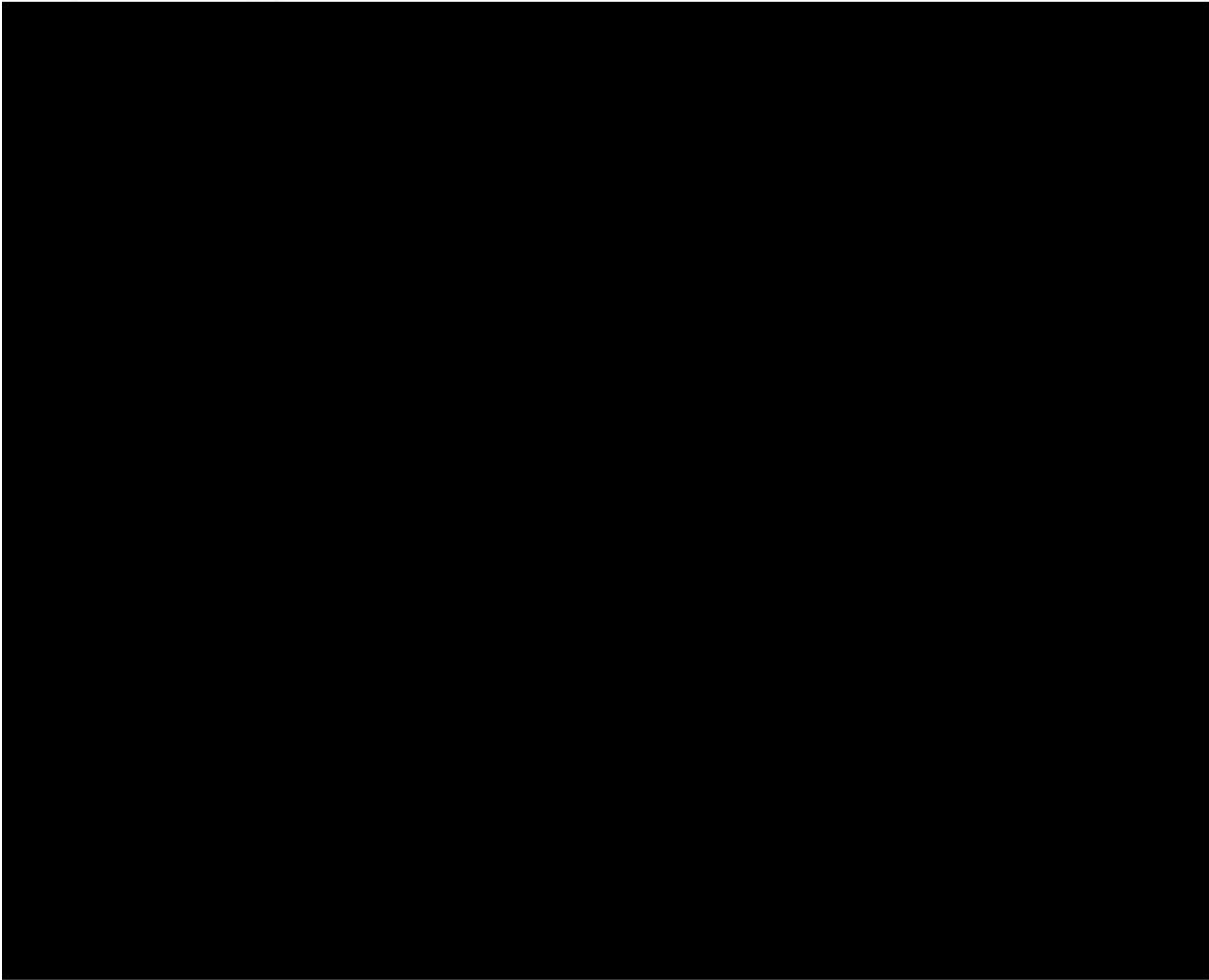
DP BARCODE No.: D4399, **FILE SYMBOL/REG. No.:** 89966-RU; **PRODUCT NAME:** Thiobencarb
Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

$$\text{A.I. (\% w/w)} = \frac{\text{Mean Sample Area ratio} \times \text{Standard weight} \times \text{Standard Purity}}{\text{Mean Standard Area Ratio} \times \text{Sample Weight}}$$

DP BARCODE No.: D4399, FILE SYMBOL/REG. No.: 89966-RU; PRODUCT NAME: Thiobencarb
Technical; DECISION No.: 528802; PC Code(s): 108401; ACTION CODE: R334; FOOD Use: Yes

Confidential Appendix

830.1600 (description of materials used to produce the product)
(MRID No. 50222201)



Manufacturing process information may be entitled to confidential treatment

DATA EVALUATION RECORD

THIOBENCARB TECHNICAL

STUDY TYPE: PRODUCT CHEMISTRY REVIEW

OCSPP 830.1550; 830.1600; 830.1620; 830.1670; 830.1700; 830.1750; 830.1800; 830.6302;
830.6303; 830.6304; 830.6313; 830.6314; 830.6315; 830.6316; 830.6317; 830.6319; 830.6320;
830.6321; 830.7000; 830.7050; 830.7100; 830.7200; 830.7220; 830.7300; 830.7370; 830.7520;
830.7550

MRIDS 50222201, 50222202, 50222203, 50222204, 50222205, 50222206

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Prepared by
Summittec Corporation
9724 Kingston Pike, Suite 503
Knoxville, Tennessee 37922

Task Order No. Active-13

Primary Reviewer:
Maolian Chen, Ph.D.

Signature: Maolian Chen ^{AE}
Date: 11/11/2017

Secondary Reviewers:
Thomas C. Marshall, Ph.D., DABT (1981 - 2016)

Signature: Thomas C. Marshall ^{AE}
Date: 11/01/2017

Robert H. Ross, M.S., Project Manager

Signature: Robert H. Ross ^{AE}
Date: 11/01/2017

Quality Assurance:
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds
Date: 11/01/2017

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.
Summittec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-16-019.

(b)

Screen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D439991; **FILE SYMBOL No.:** 89966-RU (screen); **PRODUCT NAME:** Thiobencarb Technical; **DECISION No.:** 528802; **PC Code(s):** 108401; **ACTION CODE:** R334; **FOOD Use:** Yes

DATE OUT: May 15, 2017

SUBJECT: 45/90-day screen results for technical product "Thiobencarb Technical"

FROM: Shyam Mathur, Product Chemistry Team Leader, CITAB / RD (7505P)

SPB

TO: Lisa Pahel / Shaja Joyner, RM 20; Fungicide-Herbicide Branch / RD (7505P)

Company Name: Greenfield Marketing Ltd.
Active Ingredient(s): Thiobencarb (95.9%)
MRID No(s): MRID Nos.: 50222201 to -06

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted. Data for the guidelines 830.1620 & 830.1700 for each production sites provide.

Group B: All required data submitted.

CSF: Proposed Basic CSF (dated 04-13-2017; Site- [REDACTED] submitted.

Proposed alternate CSF #1 (dated 04-13-2017 [REDACTED])

DRAFT PRODUCT LABEL: Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 26, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC
GREENFIELDS MARKETING LTD.
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 14-APR-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 4-14-17 September 2012

Experts In-Processing Signature: B.B. Date 4-26-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>89966-RU</u>		EPA Receipt Date: <u>4-14-17</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <i>no inerts to review</i>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Documentation: (Pass) / Fail

- Required forms are complete

- Related to Reg # 87290 - TG, TL, TU

* Inserts: (Pass) / Fail

- No Inserts to review

* PRN 113: (Pass) / Fail

MRZD: 502222

JK 5-2-17

* Overall Status: (Pass) / Fail



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 25, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-528802
EPA File Symbol or Registration Number: 89966-RU
Product Name: Thiobencarb Technical
EPA Receipt Date: 14-Apr-2017
EPA Company Number: 89966
Company Name: GREENFIELDS MARKETING LTD.

JAMES WAGNER
WAGNER REGULATORY ASSOCIATES, INC
AGENT FOR GREENFIELDS MARKETING LTD.
PO BOX 640
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF
THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL
FORM;SELECTIVE DATA CITATION;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in black ink, appearing to be "J. L. ...".

Front End Processing Staff
Information Technology & Resources Management Division

7

Fee for Service

{1002230i~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 20

Receipt No.

S- 1002230

EPA File Symbol/Reg. No.

89966-RU

Pin-Punch Date:

4/14/2017

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R334.1

Granted: R334

Amount Due: \$ 19838

Parent/Child Decisions:

87290-TG

87290-TL

87290-TG

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 4/18/17

Remarks:

S: 1002230

Milestone Email: james@wagnerreg.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 89966 GREENFIELDS MARKETING LTD.

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 89966-RU Product Name: Thiobencarb Technical

Override#:

☒ Me Too Section3: 63588-4 Me Too Product Name: BOLERO TECHNICAL

Application Date: 13-Apr-2017



OPP Rec'd Date: 14-Apr-2017



Front End Date: 17-Apr-2017



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

Portal submission pkg. #18957. Registration of a new manufacturing use product with registered active ingredient Thiobencarb

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

CSF

View/Edit

From: notification@pay.gov
To: Anna.Armstrong
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Thursday, April 13, 2017 12:04:26 PM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 261RENNC
Agency Tracking ID: 75224283329
Transaction Type: Sale
Transaction Date: 04/13/2017 12:04:21 PM EDT

Account Holder Name: Brian Heinze

Transaction Amount: \$19,838.00
Card Type: AmericanExpress
Card Number: *****1011

Registration Number:
Company Name: Greenfields Marketing, Lt
Company Number: 89966
Action Code: R334.1

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

<div style="display: inline-block; vertical-align: middle; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 89966- XX RU		2. EPA Product Manager Shaja Joyner	
4. Company/Product (Name) Greenfields Marketing, Ltd. / Thiobencarb Technical		PM# 20	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 63588-4 Product Name: Bolero Technical (97.4% Thiobencarb)	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input checked="" type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)			
PRIA R334.1 submission for a new manufacturing use product with an already registered active ingredient.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James M. Wagner		Title Greenfields Marketing, Ltd.	Telephone No. (Include Area Code) (302) 635-7290 (james@wagnerreg.com)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="border: 1px solid black; padding: 10px; width: 100px; margin: 0 auto;">(Stamped)</div>
2. Signature 		3. Title Agent for Greenfields Marketing, Ltd.	
4. Typed Name James M. Wagner		5. Date April 13, 2017	

Submitted Electronically

April 13, 2017

Document Processing Desk (REGFEE)
ATTN: Ms. Shaja Joyner, PM Team No. 20
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



Dear Ms. Joyner

**Subject: Greenfields Marketing, Ltd., Company No. 89966
Thiobencarb Technical
Application to register a new manufacturing use product (PRIA R334.1)**

Wagner Regulatory Associates, Inc., as agent for Greenfields Marketing Ltd., (Co. No. 89966) is requesting registration of the above referenced product containing the currently registered active ingredient Thiobencarb (PC code 108401).

Please note that this submission is a PRIA Primary Application (R334.1) that is linked to three Secondary Applications (R334.2) which are all being submitted at the same time. The primary application is submitted for Greenfields Marketing Ltd which is a subsidiary company of Willowood LLC. The secondary applications are:

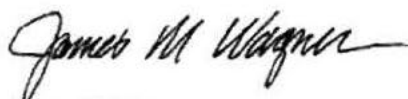
1. Willowood Thionil EC
2. Willowood Thioben 8EC
3. Willowood Thio UltraMax

In support of this application, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Greenfields Marketing, Ltd., appointing Wagner Regulatory Assoc., Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (internal and public copies) (8570-35)
- Data Transmittal Document
- Data reports as outlined in the Transmittal Document
- Draft labeling
- Certification with Respect to Label Integrity
- Confirmation of payment of PRIA fee for category R334.1 (\$19,838)

If you have any questions about this submission, please contact the undersigned at 302-635-7290 or at james@wagnerreg.com.

Respectfully Submitted,



James M. Wagner
Agent for Greenfields Marketing, Ltd.
Enclosures

DATA TRANSMITTAL DOCUMENT**1. Name and Address of Submitter**

Greenfields Marketing, Ltd.
c/o Wagner Regulatory Associates
P.O. Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration – PRIA R334.1
Thiobencarb Technical

3. Transmittal Date

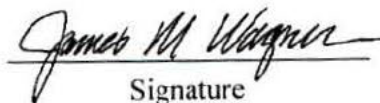
April 13, 2017

4. List of Submitted Studies

50222201	Thiobencarb Technical - Product Identity and Composition, Description of Materials, Description of Production Process, Discussion of Formation and Toxicity of Impurities, and Certified Limits, OPPTS: 830.1550, 830.1600, 830.1620, 830.1670, 830.1750
50222202	Five-Batch analysis of Thiobencarb TC, Study No. 0191, OPPTS: 830.1700, 830.1800
50222203	Preliminary Analyses To Determine The Chemical Composition Of Five Batches Of Thiobencarb Technical And Enforcement Analytical Methods For Thiobencarb Technical, Study No. BIO-ANM 411, OPPTS: 830.1700, 830.1800
50222204	Physical and Chemical Characteristics of Thiobencarb Technical, Study No. ARC-EX-1967-007-P-2, OPPTS: 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7050, 830.7100, 830.7220, 830.7300
50222205	Storage Stability and Corrosion Characteristics of Thiobencarb Technical, Study No. ARC-EX-1968-010-P-2, OPPTS: 830.1800, 830.6317, 830.6320
50222206	Thiobencarb Technical: Product Chemistry – Group B: Literature Citations and Rationales for Waiver for Certain Physical / chemical Properties Data, OPPTS Guidelines: 830.6313; 830.6315; 830.6316; 830.6319; 830.6321; 830.7200; 830.7370; 830.7520; 830.7550; 830.7840; 830.7950

Company Official:

James M. Wagner
Authorized Agent


Signature

Company Name: Greenfields Marketing Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Greenfields Marketing, Ltd., P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 89966-XX RU
Active Ingredient(s) and/or representative test compound(s) Thiobencarb	Date April 13, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Crop & Terrestrial Nonfood Crop	Product Name Thiobencarb Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

James M. Wagner

Date

04/13/2017

Typed or Printed Name and Title

James M. Wagner, Agent



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: April 13, 2017

EPA Reg No./File Symbol:
89966-XX **RU**Page
1 of 9

Applicant's/ Registrant's
Name & Address:
Greenfields Marketing, Ltd.
c/o Wagner Regulatory Associates Inc.
P.O. Box 640, Hockessin, DE 19707

Product:
Thiobencarb Technical

Ingredient: Thiobencarb

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830 Series Group A	Product Identity, Materials, Production Process, Impurities; Certified Limits	50222201	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.1700	Preliminary Analysis	50222202 50222203	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.1800	Enforcement Analytical Method	50222202 50222203 50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6302, 6303, 6304	Color, Physical State, Odor	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6313	Stability to normal and elevated temperatures	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6314	Oxidation/Reduction	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6315	Flammability	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6316	Explosibility	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6317	Storage Stability	50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6319	Miscibility	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6320	Corrosion Characteristics	50222205	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.6321	Dielectric Breakdown voltage	50222206	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.7000	pH	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
830.7050	UV/Visible Absorption	50222204	Greenfields Marketing, Ltd. Dubai, UAE	Own	
Signature <i>James M. Wagner</i>	Name and Title Jim Wagner, Agent			Date April 13, 2017	

EPA Form 8570-35 (9-97) Electronic and Paper versions available.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
830.7100	Viscosity	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7200	Melting Point		Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7220	Boiling Point	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7300	Density	50222204	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7370	Dissociation Constant	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7520	Particle size, fiber diameter and particle distribution	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7570	Octanol Water Partition Coefficient	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7840	Solubility in Water and Organic Solvents	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
830.7950	Vapor Pressure	50222206	Greenfields Marketing, Ltd.	Dubai, UAE	Own		
870.1100	Acute oral toxicity - rat	42130701	Chevron Chemical	Ramon, CA	OLD		
870.1200	Acute dermal toxicity	45104602	Valent USA	Walnut Creek, CA	OLD		
870.1300	Acute inhalation toxicity - rat	44797404	Valent USA	Walnut Creek, CA	OLD		
870.2400	Primary eye irritation - rabbit	81899	The Scotts Company	Marysville, OH	OLD		
870.2500	Primary dermal irritation	44797407	Valent USA	Walnut Creek, CA	OLD		
870.2600	Dermal sensitization	44797408	Valent USA	Walnut Creek, CA	OLD		
870.6100	Delayed neurotoxicity (acute) - hen	84135; 135284	The Scotts Company	Marysville, OH	OLD		
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent			Date April 13, 2017	

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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical			
Ingredient: Thiobencarb							
870.6200	Acute neurotoxicity - rat	42987001	Valent USA	Walnut Creek, CA	OLD		
870.3100	90-day Oral - rodent	164576; 116150	International Mineral		OLD		
870.3150	90-day Oral - non-rodent	116151	International Mineral		OLD		
870.3200	21/28-day Dermal	42893001	Valent USA	Walnut Creek, CA	OLD		
870.3465	90-day Inhalation - rat	49119310	K-I Chemical	White Plains, NY	PAY		
870.6200	90-day Neurotoxicity - rat	43001001	Valent USA	Walnut Creek, CA	OLD		
870.4100	Chronic oral - rodent	125717; 148570; 154506; 150894; 150139	The Scotts Company	Marysville, OH	OLD		
870.4200	Carcinogenicity - two rodent species - rat and mouse preferred	86004; 125717; 148570; 154506; 150894; 150139	The Scotts Company	Marysville, OH	OLD		
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	86873; 115248; 13866; 164313	The Scotts Company	Marysville, OH	OLD		
Signature <i>James M. Wagner</i>			Name and Title Jim Wagner, Agent			Date April 13, 2017	
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Applicant's/ Registrant's Name & Address:
 Greenfields Marketing, Ltd.
 c/o Wagner Regulatory Associates Inc.
 P.O. Box 640, Hockessin, DE 19707

Product:
 Thiobencarb Technical

Ingredient: Thiobencarb

870.38	Reproduction and fertility effects	154507; 40446201	The Scotts Company	Marysville, OH	OLD	
870.63	Developmental neurotoxicity				GAP	
870.51	Bacterial reverse mutation assay	84131	The Scotts Company	Marysville, OH	OLD	
870.53	In vitro mammalian cell assay	40352401; 46059801;	The Scotts Company Valent USA	Marysville, OH Walnut Creek, CA	OLD; PAY	
870.5385	In vivo cytogenetics	40352402	The Scotts Company	Marysville, OH	OLD	
870.5395	In vivo cytogenetics	84132	The Scotts Company	Marysville, OH	OLD	
870.7485	Metabolism and pharmacokinetics	87202; 42340302; 49119309	The Scotts Company K-I Chemical K-I Chemical	Marysville, OH White Plains, NY	OLD; PAY	
870.7600	Dermal penetration	45206001 49828403; 49828404	K-I Chemical Valent USA Valent USA	Walnut Creek, CA	PAY	
870.7800	Immunotoxicity	49119311	K-I Chemical	White Plains, NY	PAY	
850.2100	Avian oral toxicity	49681002; 42600201	K-I Chemical	White Plains, NY	PAY OLD	
850.2200	Avian dietary toxicity	25779; 34763 44846206	The Scotts Company Valent USA	Walnut Creek, CA	OLD	

Signature

Name and Title
 Jim Wagner, Agent

Date
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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707		Product: Thiobencarb Technical	

Ingredient: Thiobencarb

850.23	Avian reproduction	43075401; 45140601;	Valent USA	Walnut Creek, CA	OLD	
850.101	Acute toxicity daphnia	25788; 25789; 79118	The Scotts Company	Marysville, OH	OLD	
850.1025	Acute toxicity oyster	25784; 25785; 79114; 79115	The Scotts Company	Marysville, OH	OLD	
850.1035	Acute toxicity mysid	25787	The Scotts Company	Marysville, OH	OLD	
850.1045	Acute toxicity penaeid	25787	The Scotts Company	Marysville, OH	OLD	
850.1055	Acute bivalve embryo larvae	79115	The Scotts Company	Marysville, OH	OLD	
850.1075	Freshwater fish toxicity	25783; 49681001	Th Scotts Company K-I Chemical	Marysville, OH White Plains, NY	OLD PAY	
850.1300	Aquatic invertebrate life cycle (freshwater) daphnia	42680401	K-I Chemical	White Plains, NY	OLD	
850.1350	Aquatic invertebrate life cycle (saltwater)	25787	The Scotts Company	Marysville, OH	OLD	
850.1400	Fish early-life stage (freshwater)				GAP	
850.1400	Fish early-life stage (saltwater)				GAP	
850.1500	Fish life cycle	49975901; 49119306	K-I Chemical	White Plains, NY	PAY	
850.1710	Aquatic organisms bioavailability, biomagnification, toxicity	139051; 42460401	k-I Chemical The Scotts Company	White Plains, NY	OLD	
850.1950	Simulated or actual field testing for aquatic organisms	165066; 139048; 43442501	Valent USA	Walnut Creek, CA	OLD	
850.1735	Whole sediment: acute freshwater invertebrates 10 day	44628602	Valent USA	Walnut Creek, CA	OLD	

Signature <i>James M. Wagner</i>	Name and Title Jim Wagner, Agent	Date April 13, 2017
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Applicant's/ Registrant's Name & Address: Greenfields Marketing, Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, Hockessin, DE 19707				Product: Thiobencarb Technical	
Ingredient: Thiobencarb					
850.1740	Whole sediment: acute marine invertebrates 10 day				GAP
850.1740	Whole sediment: chronic invertebrates freshwater and marine	46091402	Valent USA	Walnut Creek, CA	OLD
850.3020	Honeybee acute contact toxicity	46059804	Valent USA	Walnut Creek, CA	OLD
850.3030	Honey bee toxicity of residues on foliage				GAP
850.3040	Field testing for pollinators				GAP
850.4200 850.4225 850.4250	Seed Germination, Seed Emergence and Vegetative Vigor	41690902; 44846201	Chevron Chemical; Valent USA	Ramon, CA Walnut Creek, CA	OLD
850.4400 850.4500	Aquatic Plant Toxicity	41215308; 41690901	Chevron Chemical; The Scotts Company	Ramon, CA Marysville, OH	OLD
835.2120	Hydrolysis	42130704	Chevron Chemical	Ramon, CA	OLD
835.2240	Photodegradation in water	42257801	K-I Chemical	White Plains, NY	OLD
835.2410	Photodegradation on soil	41215312	The Scotts Chemical	Marysville, OH	OLD
835.4100	Aerobic soil	42015301; 43300401; 49119303	Valent USA Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD OLD PAY
835.4200	Anaerobic soil	43252001; 49119301	Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD PAY
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Ingredient: Thiobencarb					
835.4300	Aerobic aquatic	49119302	K-I Chemical	White Plains, NY	PAY
835.4400	Anaerobic aquatic	49119304	K-I Chemical	White Plains, NY	PAY
835.1230	Leaching and adsorption/desorption	43150601; 43121201	Valent USA	Walnut Creek, CA	OLD
835.1240	Leaching and adsorption/desorption	49828402	Valent USA	Walnut Creek, CA	PAY
835.1410	Volatility - laboratory	124730; 44493; 49924	The Scotts Company	Marysville, OH	OLD
835.8100	Volatility - field				GAP
835.6100	Terrestrial	155451; 42003404	The Scotts Company; Chevron Chemical	Marysville, OH	OLD
835.6200	Aquatic (sediment)	43404005	Valent USA	Walnut Creek, CA	OLD
835.2120	Hydrolysis	42130704	Chevron Chemical	Ramon, CA	OLD
835.2240	Photodegradation in water	42257801	K-I Chemical	Walnut Creek, CA	OLD
835.2410	Photodegradation on soil	41215312	The Scotts Chemical	Marysville, OH	OLD
835.4100	Aerobic soil	42015301; 43300401; 49119303	Valent USA Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD OLD PAY
835.4200	Anaerobic soil	43252001; 49119301	Valent USA K-I Chemical	Walnut Creek, CA White Plains, NY	OLD PAY
835.4300	Aerobic aquatic	49119302	K-I Chemical	White Plains, NY	PAY
835.4400	Anaerobic aquatic	49119304	K-I Chemical	White Plains, NY	PAY
835.1230	Leaching and adsorption/desorption	43150601; 43121201	Valent USA	Walnut Creek, CA	OLD
835.1240	Leaching and adsorption/desorption	49828402	Valent USA	Walnut Creek, CA	PAY
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Ingredient: Thiobencarb					
835.1410	Volatility - laboratory	124730; 44493; 49924	The Scotts Company	Marysville, OH	OLD
835.8100	Volatility - field				GAP
835.6100	Terrestrial	155451; 42003404	The Scotts Company; Chevron Chemical	Marysville, OH Ramon, CA	OLD
835.6200	Aquatic (sediment)	43404005	Valent USA	Walnut Creek, CA	OLD
860.1300	Nature of the residue in plants	42384701	K-I Chemical	White Plains, NY	OLD
860.1300	Nature of the residue in livestock	42340301; 43404002; 43492301	K-I Chemical; Valent USA; Valent USA	White Plains, NY Walnut Creek, CA	OLD
860.1850	Confined rotational crops				GAP
860.1340	Residue analytical methods	42023; 42024; 47614; 47615; 47616; 47617; 47618	The Scotts Company	Marysville, OH	OLD
860.1360	Multiresidue method	43075402	Valent USA	Walnut Creek, CA	OLD
860.1380	Storage stability	42003405; 42384702	Chevron; K-I Chemical	White Plains, NY	OLD
860.1500	Crop field trials	124233; 124278; 40774601; 40774602; 42384702	The Scotts Company The Scotts Company K-I Chemical; The Scotts Company; The Scotts Company	Marysville, OH White Plains, NY	OLD
Signature <i>James M. Wagner</i>		Name and Title Jim Wagner, Agent			Date April 13, 2017



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Ingredient: Thiobencarb							
860.1520	Processed food or feed	42987002	Valent USA	Walnut Creek, CA	OLD		
860.1480	Meat/milk/poultry/eggs	125228; 42962801	The Scotts Company Valent USA	Marysville, OH Walnut Creek, CA	OLD		
860.1400	Potable water	43404003	Valent USA	Walnut Creek, CA	OLD		
860.1400	Fish	139051; 42460401	k-I Chemical The Scotts Company	White Plains, NY Marysville, OH	OLD		
860.1400	Irrigated crops	43148201; 43404001	Valent USA	Walnut Creek, CA	OLD		
860.1900	Field rotational crops	39114; 41609011	The Scotts Company; Chevron Chemical	Marysville, OH	OLD		
Subpart K - Human Exposure (Series 875)	Applicator Exposure and Post Application Exposure Data	CITE ALL	Ag Handlers Exposure Task Force Ag Reentry Exposure Task Force	Macon, MO Washington, DC	PAY		
Subpart L - Spray Drift	Spray Drift Data	CITE ALL	Spray Drift Task Force	Washington, DC	OLD		
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